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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,124

10/03/2006

Abraham J. Domb

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11/08/2011

THE NATH LAW GROUP

112 South West Street

Alexandria, VA 22314

EXAMINER

HALL, DEANNA K

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

11/08/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,124	Applicant(s) DOMB ET AL.	
	Examiner DEANNA K. HALL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/1/11.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 9/1/11.
2. In the reply, the applicant amended claim 18 and added new claim 36. Claims 1-36 are pending with claims 1-17 being withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 18-22, 26-29, 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al. (US 4,250,878) ("Jacobsen") in view of Sun et al. (US 2002/0115957) ("Sun").** Jacobsen discloses a porous structure 82, 86 capable of absorbing and holding at least 30% w/w aqueous solutions without dissolving or disintegrating C5L21-22, the porous structure comprising a surface area of contact 82 with the tissue C5L16-20.
5. Jacobsen discloses the invention as substantially claimed; however, Jacobsen does not directly disclose a data transmitting module capable to transmit data indicative

Art Unit: 3767

of one or more of sponge size and surface area of contact of the sponge with tissue of a subject are intended use limitations. Sun, in the analogous art, teaches a data transmitting module [0087]. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Jacobsen with the data transmitting module to ensure safety of the delivery operation. The transmitting module of Sun is a chip 622, Fig. 6. It is inherent that the transmitting module is coated with a water protecting coat as to not disrupt the electronic conductivity with the electronic control unit 626 and conductive wire 624. The chip is a type of micro transmitter.

The porous structure of Jacobsen could also comprise a non-hydrophilic polymer such as polyurethane and a hydrophilic substance having at least one functional group such as a hydroxyl group [0050] as taught by Sun.

The object of Jacobsen is to by iontophoresis, delivery a chemical species into the skin or tissue of a person and to provide such a method and bioelectrode which may be used on irregular skin surfaces to facilitate substantially uniform contact with skin surfaces having a variety of shapes C1L65-C2L10. Thus, it the examiner's position that the device of Jacobsen could be used on eye tissue being sclera tissue or cornea tissue; the surface area of contact being a substantially planar surface.

Jacobsen discloses the delivery of a charged drug, see abstract, but does not further disclose specific chemical species to be delivered. The sponge (reservoir) of Sun comprises a charged drug [0050] such as an anesthetic [0003]; or an antibiotic such as gentamycin [0027] for delivery.

6. Claims 23-25, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen in view of Sun further in view of Nicolais et al. (US 5,645,592) (“Nicolais”).

Jacobsen/Sun discloses the invention as substantially claimed (see above). However, the sponge of Jacobsen/Sun is not specifically disclosed as being comprised of a HEMA-methyl methacrylate copolymer. Sponges and hydrogels are known equivalents to those skilled in the art. Nicolais, in the analogous art, teaches the use of a hydrogel comprised of a HEMA-methyl methacrylate copolymer C7L20-44 in order to increase water absorption. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the sponge of Jacobsen/Sun by coating it with HEMA-methyl methacrylate copolymer as taught by Nicolais for the purpose of increasing water absorption.

Claim 30 is interpreted as a product by process claim (see MPEP 2113) which is read as a product claim. Thus, the sponge of Jacobsen/Sun/Nicolais is made of a hydroxyl methyl acrylate and ethylene glycol dimethacrylate copolymer.

Response to Arguments

7. Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that, whether taken alone or in combination, Jacobsen and Sun do not teach or suggest a sponge having tissue contacting surface area, a porous structure which is capable of absorbing and holding at least 30% w/w of an aqueous solution of

charged drug. This argument is not persuasive. Examiner maintains that the porous structure of Jacobsen (80 as a whole could be interpreted as the porous structure) comprises a surface area 82 of contact with the tissue C5L20-22 (specifically discloses the pouch 82 as being microporous). The porous structure is both 86 and 82 and not just 86 as applicant's arguments suggest.

Further, applicant argues that there is no suggestion or motivation to modify the apparatus of Jacobsen to remove the exterior pouch/wall such that the sponge would directly contact tissue. Examiner is unclear of this argument because this modification was not suggested by examiner. It is unnecessary to remove the exterior pouch 82 in order for the porous structure to contact the tissue because in fact the exterior pouch 82 is in itself a porous structure that contacts the tissue C5L20-22.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3767

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEANNA K. HALL whose telephone number is (571)272-2819. The examiner can normally be reached on M-F 11:00am-7:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DEANNA K HALL/
Examiner, Art Unit 3767

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3763